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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,970	08/10/2001	Ashok Amin	AMIN4A	4363

7590 02/09/2004

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EXAMINER	
WORTMAN, DONNA C	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/925,970	AMIN ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *please see attached*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *19-33*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *please see attached*

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit: 1648

The amendment after final filed 18 December 2003 will not be entered since its entry would raise a new issue under at least 35 USC 112, second paragraph. In particular, newly presented claim 40 is drawn to a method for "treating hepatitis" comprising administering to a patient an effective amount of a compound that "reduces viral levels." It is not clear whether there is any relationship between the hepatitis recited in the preamble of the claim and the "viral levels" that are recited in the body of the claim; that is, it is not clear whether the claim is intended to be limited to treating viral hepatitis, and it is not clear whether the viral levels to be reduced are levels of hepatitis virus.

If claim 40 had been limited to a method of treating viral hepatitis (e.g., drawn so as to read "A method for treating viral hepatitis") the amendment after final would have been entered, and the rejections as previously offered under 35 USC 102(b) would have been overcome.

With respect to the rejection under 35 USC 112, first paragraph, Applicant has argued that since infliximab and etanercept have been used to treat rheumatoid arthritis and are known to work by neutralizing the effects of TNF-alpha, and since hepatitis C virus has been reported to induce TNF-alpha and that TNF-alpha has been shown to induce hepatitis "when injected into humans and rodents," one skilled in the art could readily determine a dosage of either infliximab or etanercept that would be useful in treating hepatitis without undue experimentation. Applicant has additionally argued that since the present inventors have demonstrated that neutralizing the effects of TNF-alpha was

successful in treating a patient with hepatitis, the example provided should suffice to demonstrate that the invention works.

These arguments have been considered but not found persuasive. Insofar as Applicant's remarks are directed to unentered claims 34-42, they are not persuasive since the newly presented claims have not been entered into the case.

To the extent that Applicant's remarks are deemed to apply as well to previously pending claims 19-33, they will be addressed here. With respect to Applicant's assertion that hepatitis C virus has been reported to induce TNF-alpha and that TNF-alpha has been shown to induce hepatitis "when injected into humans and rodents," so that one skilled in the art could readily determine a dosage of either infliximab or etanercept that would be useful in treating hepatitis without undue experimentation, the relevance of this assertion to establishing enablement of claims by the as-filed specification is not understood, since the rejection did not rely on the inability of one of skill in the art to determine dosage without undue experimentation. With respect to Applicant's assertion that since the present inventors have demonstrated that neutralizing the effects of TNF-alpha was successful in treating a patient with hepatitis, the example provided should suffice to demonstrate that the invention works, at best Applicant has shown that treating a single patient with both rheumatoid arthritis and chronic hepatitis C did not result in a worsening of the patient's hepatitis C but does not demonstrate that neutralizing the effects of TNF-alpha results in lowering viral levels; Applicant's specification does not teach how to treat patients with all types

of hepatitis, or even all types of viral hepatitis, without undue experimentation and with a reasonable expectation for success. The rejection is maintained for these reasons and for the reasons already of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 571-272-0913. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

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